

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

MILLENNIUM PHARMACEUTICALS,	)	
INC.	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 16-1255 (GMS)
	)	
MSN LABORATORIES PRIVATE LTD. and	)	
MSN PHARMACEUTICALS, INC.,	)	
	)	
Defendants.	)	

**STIPULATION REQUESTING ENTRY OF AMENDED JUDGMENT**

WHEREAS Plaintiff Millennium Pharmaceuticals, Inc. (“Millennium”) is the holder of New Drug Application No. 21-602 by which the FDA granted approval for VELCADE® for Injection, a proteasome inhibitor, for intravenous or subcutaneous administration for the treatment of patients with multiple myeloma and patients with mantle cell lymphoma;

WHEREAS VELCADE® for Injection, or its use, is covered by one or more claims of U.S. Patent Nos. 6,713,446 (the “’446 patent”) and 6,958,319 (the “’319 patent”), which have been listed in connection with VELCADE® for Injection in the FDA’s publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the “Orange Book.”;

WHEREAS Defendants MSN Laboratories Private Ltd. and MSN Pharmaceuticals, Inc. (collectively, “MSN”) have filed Abbreviated New Drug Application (“ANDA”) No. 209622 for approval to manufacture and sell a generic version of VELCADE® for Injection prior to the expiration of U.S. Patent Nos. 6,713,446 (“the ’446 patent”) and 6,958,319 (“the ’319 patent”), which have been listed in connection with VELCADE® for Injection in the FDA’s publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the “Orange Book.”;

WHEREAS Defendants stipulated to infringement of claims 20, 31, 49, and 53 of the '446 patent (the "Asserted Claims") (D.I. 15, 16);

WHEREAS the parties' claims and counterclaims relating to the '319 patent have been dismissed with prejudice (D.I. 15, 16);

WHEREAS in *Millennium Pharmaceuticals, Inc. v. Sandoz Inc., et al.*, No. 12-1011 (GMS) (the "Sandoz Case"), the Court ordered and adjudged that the Asserted Claims are invalid due to obviousness ("the Sandoz Judgment");

WHEREAS the Court subsequently entered judgment in this action based on the Sandoz Judgment (D.I. 15, 17);

WHEREAS in *Millennium Pharmaceuticals, Inc. v. Sandoz Inc. et al.*, No. 15-2066, the Court of Appeals for the Federal Circuit reversed the Sandoz Judgment, holding that the Asserted Claims are not invalid due to obviousness;

WHEREAS the validity of the Asserted Claims is challenged in the Sandoz Case and in Civil Action Nos. Nos. 13-1874, 14-1156, 15-0040, 15-0539, 15-0540, 15-0702, 15-0804, 15-0998, 16-0034, 16-0223, 17-422, and 17-423 (the "Related Cases");

NOW THEREFORE, subject to the approval of the Court, the parties hereby stipulate and agree:

1. To entry of final judgment in this action in the form attached hereto as Exhibit A; and
2. That in the event that the ultimate outcome of the pending challenges to the validity of the Asserted Claims (*i.e.*, the Sandoz Case and the Related Cases), including the resolution of any appeals and petitions for writ of certiorari that may arise therefrom, is that all of

the Asserted Claims are invalid, the parties will jointly request that the Court further amend this final judgment within 30 days thereafter.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Maryellen Noreika*

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SO ORDERED this \_\_\_\_ day of January 2018.

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UNITED STATES DISTRICT COURT JUDGE